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10/586,020	07/18/2008	Morteza Naghavi	1362001-2068.1	9352

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EXAMINER	
EVOY, NICHOLAS LANE	
ART UNIT	PAPER NUMBER
3768	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,020	NAGHAVI ET AL.	
	Examiner	Art Unit	
	NICHOLAS L. EVOY	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,42-52 and 55-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,42-52 and 55-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 42-60, 62 and 71-77 rejected under 35 U.S.C. 103(a) as being unpatentable over Young, US Patent 6,219,572 B1, in view of Rafter et al, US PG Pub Number 2003/0163048 A1.

1. Regarding claim 1, Young teaches a method comprising the steps of : positioning a probe adjacent a tissue site of an animal including a human; acquiring pre-injection data of the tissue site; injecting a contrast agent into the animal at an injection site; acquiring post-injection data of the tissue site; performing a difference analysis between pre-injection data and post-injection data to detect, localize, and quantify anatomical, morphological and/or functional features of the tissue site (Column 1, Line 55 – Column 2, Line 36).

2. Young does not teach obtaining phase-correlated pre-injection data from the pre-injection data and phase-correlated post-injection data from the post-injection data by correlation of the pre-injection data and post-injection data with a cardiac phase. Rafter teaches an ultrasonic, micro-bubble contrast imaging system and method in which the imaging system is synchronized to the patient heart cycle to produce cardiac-phase correlated data (Paragraphs 32, 41, 52-54, 57 and 59).

3. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Young and Rafter because both inventions are directed to contrast-based imaging systems and methods and by correlating the imaging process with the cardiac phase of the patient, the effect of motion in the image would be decreased thereby clarifying the image and improving the diagnostic effectiveness of the method (Rafter: Paragraph 41).

4. Regarding claim 42, Young discloses the method of claim 1, further comprising the steps of: prior to the injecting step, positioning a contrast agent delivery system adjacent the injection site (Column 3, Lines 3-24).

5. Regarding clam 43, Young discloses the method of claim 1, wherein the pre-injection data comprises a pre-injection data sequence of the tissue site acquired over a pre-injection period of time (Column 1, Line 56 – Column 2, Line 36).

6. Regarding claim 44, Young discloses the method of claim 1, wherein the post-injection data comprises a post-injection data sequence of the tissue site acquired over a post-injection period of time (Column 1, Line 56 – Column 2, Line 36).

7. Regarding claim 45, Young discloses the method of claim 1, wherein the difference analysis is between the pre-injection data sequence and post-injection data sequence (Column 3, Lines 25-60).

8. Regarding claim 46, Young discloses the method of claim 1, wherein the injection site comprises a vessel (Column 1, Lines 56-65).

9. Regarding claim 47, Young discloses the method of claim 46, wherein the vessel comprises an artery supply blood to the tissue site or a vein removing blood from the tissue site (Column 1, Lines 56-65).

10. Regarding claim 48, Young discloses the method of claim 46, wherein the tissue site is a vessel and the step of positioning the probe comprises the steps of: positioning a guide-catheter in the vessel; and positioning, on the guide-catheter, a micro-catheter including the probe in the vessel adjacent the tissue site (i.e. catheter and injector and tube, Column 3, Lines 3-24).

11. Regarding claim 49, Young discloses the method of claim 1, further including the step of: acquiring during injection data sequence, wherein the performing step further includes difference analyses of the pre-injection, during-injection and post-injection data sequences (Column 3, Lines 25-60).

12. Regarding claim 50, Young discloses the method of claim 1, wherein the data comprises ultrasonic data (Column 3, Lines 50-53).

13. Regarding claim 51, Young discloses the method of claim 49, wherein the data comprises ultrasonic data (Column 3, Lines 50-53).

14. Regarding claim 52, Young discloses the method of claim 1, wherein the pre-injection data comprises a pre-injection data sequence of the tissue site acquired over a pre-injection period of time and the post-injection data comprises a post-injection data sequence of the tissue site acquired over a post-injection period of time (Column 1, Line 56 – Column 2, Line 36).

15. Regarding claim 53, Young discloses the method of claim 52, further comprising the step of: forming pre phase-correlated data from the pre-injection data and post phase-correlated data from the post-injection data (i.e. phase-correlated data from a phase-correlated imaging process such as MRI or ultrasound, Column 1, Line 56 - Column 2, Line 36).

16. Regarding claim 54, Young discloses the method of claim 53, further comprising the step of: selecting a region of interest within the pre and post phase-correlated data (Column 1, Lines 29-34).

17. Regarding claims 55-58, Young teaches a method as referenced above. Young does not teach the step of compensating for motion within the region of interest in the dataset. Rafter teaches an ultrasonic imaging method to detect coronary artery stenosis at rest. Rafter specifically discloses a substep of employing motion compensation techniques within a region of interest to improve visualization of the arterioles and remove imaging artifacts caused by the pulsitile nature of blood flow (Paragraph [0054]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of compensating for motion within the region of interest in the data set in the invention of Young because it is well known in the art that bodies in general, and more specifically organs and vessels (as is disclosed in Rafter) are not completely stationary and that compensating for motion would be an obvious step to avoid blurred and distorted imaging data (Paragraph [0054]).

18. Regarding claim 59, Young discloses the method of claim 52, wherein the data acquisition times are from about .5 minutes to about 30 minutes (Column 1, Lines 6-11).

19. Regarding claim 60, Young discloses the method of claim 52, wherein the pre-injection data is acquired over a pre-injection period of time ranging from about 1 second to about 10 minutes and the post-injection data is acquired over a post-injection period of time ranging from about 1 second to about 20 minutes (Column 1, Lines 6-11).

20. Regarding claim 62, Young discloses the method of claim 1, further comprising the step of: generating difference data or image sequences between data or frames in the pre- and post- injection data (Column 1, Line 56 – Column 2, Line 36).

21. Regarding claim 71, Young discloses the method of claim 1, wherein the probe is selected form the group consisting of an ultrasound probe, a variable frequency ultrasound probe, a magnetic probe, a photonic probe, a near infrared probe, a terahertz probe, microwave probe and combinations thereof (i.e. ultrasound, Column 3, Lines 50-53).

22. Regarding claim 72, Young discloses the method of claim 1, wherein the contrast agent is selected from the group consisting of microbubbles, magnetically active microbubbles, magnetically active nanoparticles, near Infrared visible microbubbles, near Infrared visible nanoparticles, optically visible microbubbles, optically visible nanoparticles, terrahertz visible microbubbles, terrahertz visible nanoparticles, microwave visible microbubbles, microwave visible nanoparticles, red blood, cells including magnetically active nanoparticles, near Infrared visible nanoparticles, optically visible nanoparticles, terrahertz visible nanoparticles, microwave visible nanoparticles, and mixtures thereof, and mixtures or combinations thereof (Column 1, Lines 27-28).

23. Regarding claim 73-74, Young teaches a method as referenced above. Young does not teach the step of exposing the tissue to a sonic energy at a frequency sufficient to destroy contrast agent. Rafter teaches a method as referenced above, with the additional step of destroying microbubbles in the arterioles and capillaries using high power ultrasonic energy (Abstract and Paragraphs [0013]-[0014]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of exposing the tissue to a sonic energy at a frequency sufficient to destroy contrast agent to Young because process of rupturing microbubbles allows for a user to obtain a more optimal concentration of microbubbles in the vessel for contrast imaging (Paragraphs [0028]-[0031]).

24. Claims 61 and 63-70 rejected under 35 U.S.C. 103(a) as being unpatentable over Young, US Patent Number 6,219,572 B1, in view of Rafter et al, US PG Pub Number 2003/0163048 A1, and further in view of O'Donnell et al, US Patent Number 5,921,931.

25. Regarding claims 61, 63-65 and 69-70, Young and Rafter teach a method as referenced above.

26. Young and Rafter do not teach the steps of temporally sorting and binning data based on cardiac phase, performing noise reduction and color-coding. O'Donnell teaches a method and apparatus for creating a color blood flow image based upon ultrasonic echo signals received by an intravascular ultrasound imaging probe with the

specific features of threshold noise reduction (Column 4, Lines 5-22), color-coding (Column 9, Lines 4-63) and the binning of data values (Column 9, Lines 4-63).

27. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Young, Rafter and O'Donnell because both inventions are directed to two-phase medical imaging methods and the invention of O'Donnell is "particularly directed to displaying an image rendered by the ultrasound imaging system of the dynamic portions of the field of view in various ones of multiple colors associated with varying degrees of dynamic behavior, and wherein the colorized dynamic image is superimposed upon an image of relatively static features represented in gray scale format" (Column 1, Lines 29-40).

28. Regarding claim 66, O'Donnell teaches the method of claim 1, further comprising the step of generating an animation of changes in enhancements over the total acquisition time of the difference data or images, thresholded data or images and/or the color-coded data or images (i.e. dynamic motion power and motion frequency data displayed with varying characteristics, specifically colorization, Column 3, Line 8 - Column 4, Line 22).

29. Regarding claim 67, O'Donnell teaches the method of claim 66, wherein the animation corresponds temporally with the originally-acquired data in order to allow direct visual comparison between the original data and the processed data (i.e. comparison of static B-scan data with a mask, Figure 8, Column 13, Lines 4-54 and Column 14, Line 61 - Column 15, Line 48).

30. Regarding claim 68, O' Donnell teaches the method of claim 1, further comprising computing a statistical measurement of an average enhancement per enhanced pixel for each difference data or image generated over the total acquisition time to quantify numerically a presence and amount of enhancements over time (Column 11, Line 55 - Column 12, Line 52).

Response to Arguments

Applicant's arguments with respect to claims 1, 42-52 and 55-74 have been considered but are moot in view of the new ground(s) of rejection.

31. Regarding applicant's argument that neither Young, Rafter nor O'Donnell teach or suggest correlation of data with cardiac phase: See rejection above.

32. Regarding applicant's argument that "*The dependent claims include additional patentable features. For example, claim 61 recites automatically sorting and binning the data according to their temporal position in each of a sequence of cardiac phases over the total acquisition time. Claim 63 recites performing noise reduction on the data prior to difference analysis via mathematical averaging of temporally correlated data or frames, where temporal correlated data or images are data or images binned at a same point in a cardiac cycle. The Office Action acknowledges that Young does not teach or suggest these elements of the claims. Office Action, p. 12. The Office Action turns to O'Donnell. However, O'Donnell does not teach or suggest sorting and binning data according to temporal position in each of a sequence of cardiac pulses. To the extent that O'Donnell teaches sorting and binning, these functions are performed with respect*

to signal strength, not temporal position": Although the disclosure of O'Donnell teaches that the binning function is performed with respect to signal strength in the referenced embodiment, one of ordinary skill in the art would recognize that the binning process could be applied to any method in which data is filtered or sorted, such as the phase-segmentation process referenced in the rejection under Young and Rafter (see above). The fact that O'Donnell discloses the binning function with respect to signal strength does not limit the binning function *only* to signal strength, as would be appreciated by one of ordinary skill in the art.

33. Regarding applicant's arguments on Claims 66-68: See clarified rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICHOLAS L. EVOY/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768